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| 10/535,696 | 06/27/2005 | Katsuro Tachibana | F-8681 | 9237 |
| 28107 7590 09/19/2007 JORDAN AND HAMBURG LLP 122 EAST 42ND STREET SUITE 4000 NEW YORK, NY 10168 | | | EXAMINER LONG, SCOTT | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/535,696 | Applicant(s) TACHIBANA ET AL. | |
| | Examiner Scott D. Long | Art Unit 1633 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner acknowledges receipt of Claim amendments and Applicant's remarks, filed on 9 July 2007.

Claim Status

Claims 3-4 are amended. Claims 1-2 are withdrawn. Claims 5-15 are newly submitted. Claims 3-15 are under current examination.

Priority

This application claims benefit as a 371 of PCT/JP03/14953 11/21/2003. This application claims benefit from foreign patent applications (JAPAN) 2002-339944 (filed 11/22/2002) and 2003-389975 (filed 11/19/2003). The instant application has been granted the benefit date, 21 November 2003, from the application PCT/JP03/14953.

Response to Arguments - Claim Rejections 35 USC § 102

Response to Arguments – Tachibana et al.

Applicant's arguments, see page 6 and Claim amendments, filed 9 July 2007, with respect to claims 3-4 have been fully considered but are found to be unpersuasive.

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The applicant argues that Tachibana et al. do not teach the specific limitation of claim 3 directed to a “detachable” ultrasonic emitter.

Contrary to the applicant's assertion, Tachibana et al. teach, a description of Figure 2 in which “[t]he end tube (6) is provided with a ultrasonic element (7) (e.g. – a cylindrical ceramic oscillator, etc.). The ultrasonic element (7) is supplied by a ultrasonic signal of 20kHz to several MHz from a ultrasonic oscillation circuit (8) via a conductor (9a), connectors (10a) and (10b) provided on the side of the base tube(5)” (page 3, lines 43-44). Tachibana et al., illustrate the diagram, Figure 2 (page 7), as showing components “10a” and “10b” as the connectors. The Oxford English Dictionary defines a “connector” (*British* connector) as “*Electr.* A device for holding two parts of a conductor in intimate contact.” The examiner contends that a device with hold parts together, is inherently detachable, since in electronics, parts are separable. Therefore, the applicant asserts that Tachibana et al. do indeed teach the limitations of claim 3. The additional amendments to claim 3 are directed to the intended use of the claimed apparatus and not to limitations of the device.

The applicant further argues that Tachibana et al. do not teach the specific limitation of claim 4 directed to “a manual control unit for adjusting the frequency and intensity of the ultrasonic wave” (Remarks, page, 6). The applicant further argues, that although Tachibana et al. disclose “that an ultrasonic signal of 30 KHZ to several MHz can be applied does not mean that such a manual control unit is disclosed. It is possible, for example, for the frequency to be generated automatically without an manual control unit to control the frequency.” (Remarks, page 6, last paragraph) and

further, "There is no disclosure in Tachibana et al. of adjusting the intensity of the ultrasonic wave" (Remarks, page 7, first parag.).

Contrary to the applicant's assertion, Tachibana et al. teach changing the "energy" of the ultrasonic vibration, which the examiner interprets to mean the "intensity". Tachibana et al. teach, "In order to enhance the therapeutic effects with ultrasound, it is required to apply a higher energy of a ultrasonic vibration. However, too higher energy of an ultrasonic vibration causes disadvantageously burns or unnecessary heat at the portion other than the desired portion. On the other hand, when the energy of a ultrasonic vibration is lowered for eliminating such disadvantages, there is a problem of less effect of the ultrasound at the desired portion." (page 2, lines 19-23). In addition, Tachibana et al. teach, "[t]he desired ultrasound is applied by conventional ultrasonic devices which can supply a ultrasonic signal of 20 KHz to several MHz." (page 3, lines 30-31). Inherently, numerous "conventional ultrasonic devices" contain manual controls. Therefore, the examiner asserts that the limitations of claim 4 are taught by Tachibana et al.

Therefore, the rejection of claims 3-4 under 35 USC 102(b) as anticipated by Tachibana et al. is hereby maintained.

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Response to Arguments – Rich-Mar as evidenced by Nakashima et al.

Applicant's arguments, see page 7-8 and Claim amendments, filed 9 July 2007, with respect to claims 3-4 have been fully considered but are found to be unpersuasive.

The applicant state, "Applicant also wish to note that Nakashima et al. appears to have been redacted and that, as a result, Applicants cannot determine whether the Therasound 3.4 is actually disclosed on page 592, col.2 of Nakashima et al." (Remarks, page 8). The examiner would like to point out that Nakashima et al. is listed in the applicant's IDS for the instant application, and therefore the examiner felt it was not necessary to send a copy to the applicant. Nakashima et al. teach the Rich-Mar device for delivering therapeutic genes to teeth (page 592, col.2). The Rich-Mar device as evidenced by the teachings of Nakashima et al. demonstrate all the limitations of claims 3-4, including a detachable ultrasonic emitter.

Therefore, the rejection of claims 3-4 under 35 USC 102(b) as anticipated by Rich-Mar as evidenced by Nakashima et al. is hereby maintained.

Response to Arguments – Ram

Applicant's arguments, see page 8 and Claim amendments, filed 9 July 2007, with respect to claims 3-4 have been fully considered but are found to be unpersuasive.

The applicant asserts, "Ram fails to disclose an ultrasonic transducer. The reference in Ram to an electrically oscillated handpiece is not referring to any kind of ultrasonic transducer." (Remarks, page 8). Contrary to the applicant's assertion, Ram

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does suggest an ultrasonic transducer. Ram teaches "The toothbrush head **3** is attached to the handpiece **2** by means of a magnetostrictive stack **32** carried by the head for oscillating it, and receivable within a socket of the handpiece. The magnetostrictive stack **32** is only partially shown in FIG.2, but more fully shown in FIGS. 3, 4, and 5. Such constructions for attaching and oscillating the head of a dental implement at high frequencies are well known (e.g., as included in the above-mentioned 'Dentsply/Cavitron')." (col.4, lines 36-47). Ram et al. refers to "Dentsply/Cavitron [as an]...ultrasonic dental unit" (col.1 , lines 14-15). Therefore, the examiner believes that Ram does teach a device having an ultrasonic transducer.

Therefore, the rejection of claims 3-4 under 35 USC 102(b) as anticipated by Ram is hereby maintained.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-9 are rejected under 35 U.S.C. 103(a) as being obvious over Nakashima et al (Human Gene Therapy, April 2003, 14:591-597) in view of Rich-Mar (Therasound 3.4 Specifications, 1998, <http://www.web.archive.org/web/19981205143248/http://richmarweb.com/>) and further in view of Ram (US-5,593,304, issued 14 January 1997) and further in view of Tachibana et al (EP0504881A2, published 23 September 1992) and further in view of Sakurai et al. (US-5,391,144, issued 21 Feb. 1995).

The teachings of Nakashima et al. and Rich-Mar and Ram and Tachibana et al. are recited above in the 35 USC § 102 sections and in the previous action (filed 3/9/2007).

Claim 3 is directed to an agent delivery apparatus for delivering a therapeutic agent to a tooth or periodontal tissue, comprising an ultrasonic transducer having a tip provided with a detachable ultrasonic emitter for emitting an ultrasonic wave to a target site of a tooth or periodontal tissue, and a medical-material ejecting device for supplying

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to said target site a medical material for use in therapeutic agent delivery to a tooth or periodontal tissue by means of ultrasonic energy, comprising a mixture of microbubbles and a therapeutic agent consisting of at least one of a plasmid DNA and a drug with a therapeutic effect on a tooth or periodontal disease. Tachibana et al. teach "a drug administration device used for injecting, pouring, applying or circulating the...pharmaceutical liquid composition" (page 2, lines 42-43). Tachibana et al. also teach, "injecting the...pharmaceutical liquid composition...while applying ultrasound" (page 2, lines 35-36). Tachibana et al. teach, "desired ultrasound is applied by conventional ultrasonic devices which can supply a ultrasonic signal of 20KHz to several MHz" (page 3, lines 30-31). Tachibana et al. teach, "pharmaceutical liquid composition is directly administered to the diseased part with an appropriate device" (page 3, lines 38-39). Tachibana et al. further teach, "the drug administration device comprises...and end tube which is to be inserted into the tissue...and through which the pharmaceutical liquid composition is...injected....The end tube is provided with a ultrasonic element (e.g. – a cylindrical ceramic oscillator, etc.)...The ultrasonic element is supplied by a ultrasonic signal of 20kHz to several MHz from a ultrasonic oscillation circuit via a conductor" (page 3, lines 40-45). Tachibana et al. also describe "the tip of the end tube" (page 4, line 13). Rich-Mar sells an apparatus that emits an ultrasonic wave. Nakashima et al. teach the Rich-Mar device for delivering therapeutic genes to teeth (page 592, col.2). The Richmar device allows a choice of detachable probes. Ram teaches, a "dental apparatus includes... electrical oscillating drive" (abstract). Ram teaches that the device "includes...a manual frequency selector" (col.2, lines 10-

12) which allows the operator to "select any frequency up to 35 KHz" (ultrasonic) range (col.4, line 19). In addition to the ultrasonic waves, Ram teaches "discharge of a flowable material, e.g.,...a therapeutic...agent" (col.2, lines 4-5). Ram teaches that the device comprises "a quickly-attachable coupling...interchangeable heads" (col.3, lines 16 and 19). Ram also describes dental instruments that comprise a "metal tip" (col.1, line13). Ram teaches "The toothbrush head 3 is attached to the handpiece 2 by means of a magnetostrictive stack 32 carried by the head for oscillating it, and receivable within a socket of the handpiece. The magnetostrictive stack 32 is only partially shown in FIG.2, but more fully shown in FIGS. 3, 4, and 5. Such constructions for attaching and oscillating the head of a dental implement at high frequencies are well known (e.g., as included in the above-mentioned 'Dentsply/Cavitron')." (col.4, lines 36-47). Ram et al. refers to "Dentsply/Cavitron [as an]...ultrasonic dental unit" (col.1, lines 14-15). Therefore, the examiner believes that Ram does teach a device having an ultrasonic transducer. Tachibana et al. teach, a description of Figure 2 in which "[t]he end tube (6) is provided with a ultrasonic element (7) (e.g. – a cylindrical ceramic oscillator, etc.). The ultrasonic element (7) is supplied by a ultrasonic signal of 20kHz to several MHz from a ultrasonic oscillation circuit (8) via a conductor (9a), connectors (10a) and (10b) provided on the side of the base tube(5)" (page 3, lines 43-44). Tachibana et al., illustrate the diagram, Figure 2 (page 7), as showing components "10a" and "10b" as the connectors. The Oxford English Dictionary defines a "connector" (*British* connector) as "*Electr.* A device for holding two parts of a conductor in intimate contact." The examiner contends that a device with hold parts together, is inherently

detachable, since in electronics, parts are separable. Therefore, the applicant asserts that Tachibana et al. teach the limitations of claim 3. Sakurai et al teach, "An ultrasonic treatment apparatus comprises at least one hand piece, a plurality of probes, and an ultrasonic drive device. The hand piece has an ultrasonic oscillation device for generating ultrasonic vibration. Each probe is adapted to be attached to the hand piece and designed to transmit the ultrasonic vibration generated by the hand piece. The ultrasonic drive device is connected to the hand piece, for driving the ultrasonic oscillation device." (abstract).

Claim 4 is directed to The agent delivery apparatus as defined in claim 3, which further comprises a manual control unit including means for adjusting a frequency and an intensity of the ultrasonic wave to be generated from said ultrasonic transducer, whereby any one of a plurality of oscillation directions in said ultrasonic emitter can be selected according to changes of said frequency. As cited above, the frequency of the device can be adjusted, "the ultrasonic element is supplied by a ultrasonic signal of 20kHz to several MHz from a ultrasonic oscillation circuit via a conductor" (page 3, lines 44-45). The Rich-Mar device allows manual adjustment of "frequency, intensity" (Richmar, Specification, parag.1). Ram teaches, "a manual frequency selector for selecting the frequency of the electrical oscillating drive" (col.2, lines 11-12). Tachibana et al. teach changing the "energy" of the ultrasonic vibration, which the examiner interprets to mean the "intensity". Tachibana et al. teach, "In order to enhance the therapeutic effects with ultrasound, it is required to apply a higher energy of a ultrasonic vibration. However, too higher energy of an ultrasonic vibration causes

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disadvantageously burns or unnecessary heat at the portion other than the desired portion. On the other hand, when the energy of a ultrasonic vibration is lowered for eliminating such disadvantages, there is a problem of less effect of the ultrasound at the desired portion." (page 2, lines 19-23). In addition, Tachibana et al. teach, "[t]he desired ultrasound is applied by conventional ultrasonic devices which can supply a ultrasonic signal of 20 KHz to several MHz." (page 3, lines 30-31). Inherently, numerous "conventional ultrasonic devices" contain manual controls. Therefore, the examiner asserts that the limitations of claim 4 are taught by Tachibana et al. Sakurai et al. also teach, "means for regulating each said ultrasonic oscillator means in such a manner that the ultrasonic vibration generated by the ultrasonic oscillator means is maintained constant for each probe." (col.60, lines 39-42) and further teach, "The apparatus...wherein said ultrasonic drive means has adjusting means to adjusting the amplitude of the high-frequency voltage applied to said ultrasonic oscillation means" (col.60, lines 48-51).

Claim 5 is directed to the agent delivery apparatus according to claim 3, wherein said ultrasonic emitter has a size ranging from 1 x 0.1 x 0.1 mm to 1 x 1 x 1 cm. Sakurai et al. teach, "the distal end of the sheath 157 can have a diameter slightly greater than the sum of the diameters of the probe 4 and the pipe 235" (col.35, lines 60-62). Sakurai et al. teach, "The sheath 118 can be manufactured by molding, easily and at low cost. Its wall thickness is about 0.2 to 0.4 mm" (col.44, lines 44-45). Sakurai et al. teach, "the probe 4 can transmit the ultrasonic vibration" (col.42, lines 65-66). Sakurai et al. teach, "probe has a length which is an integral multiple of half the

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wavelength of the ultrasonic vibration transmitted from any one of said ultrasonic oscillation means" (col.64, lines 37-41). Sakurai et al. "The tip 77 has a length of $n\lambda/2$, where n is an integer and λ is the wavelength of the ultrasonic vibration" (col.13, lines 51-54). Therefore, the examiner asserts that the size limitations of the tip of the ultrasonic emitter is rendered obvious by the prior art, particularly Sakurai et al.

Claim 6 is directed to the agent delivery apparatus according to claim 3, further comprising an endoscope. Sakurai et al. teach, "the apparatus...wherein said probe-guiding means is an endoscope having observation means" (col.65, lines 4-6).

Claim 7 is directed to the agent delivery apparatus according to claim 3, further comprising an illuminator. The specification does not specifically define "illuminator", but uses the term, "illuminator/endoscope." Therefore, the examiner believes that because the applicant has not made a distinction between an illuminator and an endoscope, that the teachings of Sakurai et al. satisfy the limitation of claim 7. Sakurai et al. teach, "the apparatus...wherein said probe-guiding means is an endoscope having observation means" (col.65, lines 4-6).

Claim 8 is directed to the agent delivery apparatus according to claim 4, where said frequency ranges from 100 kHz to 10MHz. Tachibana et al. teach, "[t]he desired ultrasound is applied by conventional ultrasonic devices which can supply a ultrasonic signal of 20 KHz to several MHz." (page 3, lines 30-31). Ram teaches that the device "includes...a manual frequency selector" (col.2, lines 10-12) which allows the operator to "select any frequency up to 35 KHz" (ultrasonic) range (col.4, line 19). Sakurai et al.

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teach, "the frequency (500 kHz for example) of the high-frequency treatment signal" (col.53, lines 23-25).

Claim 9 is directed to the agent delivery apparatus according to claim 4, wherein said intensity ranges from 0.5 to 10 W/cm². Nakashima et al. teach "Ultrasound (ST1000V-W, Richmar, Inola, OK) was used at a frequency of MHz, at intensities of 0.5 W/cm² or 1.0 W/cm²" (page 592, col. 2).

Claims 10-11 are directed to the agent delivery apparatus according to claim 3 wherein said ultrasonic emitter is configured to have two (or at least two) oscillation directions corresponding to respective ultrasonic frequencies of said ultrasonic emitter. Sakurai et al. describe the ultrasonic vibration as being "axial" (col.23, lines 58-59 and col.24, line 59) and further illustrates the vibrations in Figures 40-42, which are vibrating from side to side in a variety of harmonic modes.

Claims 12-13 is directed to the agent delivery apparatus according to claim 3, further comprising a case for said ultrasonic emitter and illuminator (endoscope), said illuminator (endoscope) and said medical material ejecting device being supported by said case. Sakurai et al. teach, Figure 32A, which shows "the junction between an endoscope and the hand piece of an ultrasonic treatment apparatus" (col.3, lines 11-14). Sakurai et al. further describes their apparatus comprising a handpiece containing an ultrasonic oscillator and a vibration-transmitting member attached to the hand piece. The manner of attaching the elements of the invention are a matter of design choice.

Claims 14-15 recited limitations of adjusting ultrasonic frequency, as described above, under claim 8.

It would have been obvious to the person of ordinary skill in the art at the time of the invention was made to create an agent delivery device having a detachable ultrasonic emitter, further comprising an endoscope and illuminator for delivery of therapeutic agents.

Regarding the rationale for combining prior art elements according to known methods to yield predictable results, all of the claimed elements were known in the prior art and one skilled in the art could have combined the element as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Each of the elements (ultrasonic emitter, an endoscope and illuminator) are taught by Nakashima et al. and Rich-Mar and Ram and Tachibana et al. and Sakurai et al. and they are taught in various combinations and are used to deliver therapeutic agents. It would be therefore predictably obvious to use a combination of these three elements in a device.

Therefore the method as taught by Nakashima et al. and Rich-Mar and Ram and Tachibana et al. and Sakurai et al. would have been *prima facie* obvious over the method of the instant application.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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